Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
September 13, 2016

Board Members:

Present:

Zail Berry, MD	Louise Rosales, NP	James Marmar, RPh
Janet Farina, RPh	Clayton English, PharmD	

Absent: Patricia King, MD

Staff:

Laureen Biczak, DO Change HealthCare	Mary Beth Bizzari, RPh, DVHA	Carrie Germaine, DVHA
Scott Strenio, MD, DVHA	Jennifer Egelhof, DVHA	Laurie Brady, RPh, Change HealthCare
Jason Pope, DVHA	Stacey Baker, DVHA	Nancy Hogue, DVHA
	Joseph Olinzock, Pharmacy Intern	

Guests:

Rick Angeli, Merek	Adam Denman, GSK	Jeffrey Olsen, Gilead
Shaffee Bacchus, Janssen	Darren Keegan, Allergan	Marie Roache, Pfizer
Kristen Bruno-Doherty, Astrazeneca	Megan Walsh, Abbvie	TimMorgan, ZS Pharma
	Rodney Francisco, Sunovion	Irma Saliu, Allergan
Kristen Chopas, Gilead	Paul Short, Vertex	John Meyer, Otsuka
Scott Williams, J & J	Doris Strader, UVMMC	

1. Executive Session:

- An executive session was held from 6:15 p.m. until 6:40 p.m.

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The July meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Nancy Hogue, DVHA:

- Janet Farina, RPh, and James Marmar, RPh are ending their terms, and this will be their last meeting.
- Next meeting, the hope is to have 3 new board members, one physician and 2 pharmacists.
- Effective September 9th an automated PA for Suboxone titration was put into place. This will cut down on the provider burden of having to call the HelpDesk to get a new dosage strength approved.

4. Medical Director Update: Scott Strenio, MD, DVHA:

- Dr. Strenio read an email sent from the office of Dr. Lazarovich, Dr. Kent, and Dr. Jaffe regarding clinical criteria for Nucala. Changes to the existing criteria will be discussed later in the meeting.

5. Follow-up Items from Previous Meetings: Laureen Biczak, DO Change Healthcare & Laurie Brady, RPh Change Healthcare

- **Use of Butalbital Containing drugs initiative:**
  - The initial data presented on 7/12/16 looked at the total number of distinct members prescribed Butalbital during a defined 1-year time period. The data was then broken down into those members that received >18 tablets in ANY given 30-day period versus those that received 18 tabs or less. 74% of members identified received >18 tablets in at least one 30-day time period which suggested a significant number of members potentially overusing Butalbital. To better analyze this data and determine prescribing patterns, the board requested a breakdown of use by age, total number of tablets filled, average quantity per Rx, and the average quantity per 30 days. Although many members filled more than 18 tablets in one prescription, only 15% of members filled an average of >18 per month. Prescriber data was also analyzed for trends in prescribing practices. Most patients saw only 1 or 2 different prescribers within the year. It was also found that many prescriptions were for 30 days or less, but the quantities varied. The average quantity for most prescribers per prescription was 19-54 tablets, but some ranged as high as 94, illustrating possible individual, not wide spread over prescribing of Butalbital.

Recommendation: The recommendation is there may be benefit in targeted provider education on the appropriate use of butalbital and the risk of development of medication overuse headache and other adverse effects. There may also be opportunity to educate providers on the use of alternative medications to prevent headaches in patients with frequent, chronic headaches. Additional interventions could include the implementation of quantity limits on butalbital containing medications.

Board Decision: Change Healthcare will provide DVHA with the provider details for them to do outreach.

6. RetroDUR/DUR: Laureen Biczak, DO Change Healthcare

- **Data Presentation: Use of Angiotensin Modifying Medications in Patients with Diabetes Mellitus and Hypertension**
    - Hypertension is a common and serious problem in patients with both type 1 and type 2 diabetes. The American Diabetes Association guidelines state that pharmacologic therapy for patients with diabetes and hypertension should include either an ACE inhibitor or ARB, but not both, and that multiple drug therapy (including an ACE-I or ARB at maximal doses plus a thiazide diuretic) is generally required to meet blood pressure targets. Additionally, the target blood pressure is systolic blood pressure <140 mm Hg, and the diastolic target is < 90 mm Hg. In order to evaluate provider compliance with guidelines and possible gaps in care, we identified members with medical claims with a diagnosis of both diabetes (type I or type II) and hypertension. We then quantified the use of ACE-I and ARB medications, either alone, or combined with other antihypertensive medications, including thiazide diuretics (ARMA-angiotensin/renin modifying agents). Members with both a DM and HTN diagnosis in medical claims totaled 3,073 (100%). Those who also had a claim for an ARMA totaled 2,221 (72%). Members without a claim for ARMA totaled 852 (28%), and members without any pharmacy claims at all totalled 40 (1.3%).

Recommendation: It is difficult to ascribe a prescriber who may have a role to play in the potential gap in care (since we do not have a primary care provider identified), and since there was a potentially large cohort of members with a potential gap in care, it seems that a fairly global educational effort would be most viable.

Board Decision: The Board unanimously voted no action required.

Introduce: *Proposed RetroDUR Initiatives for 2017*

- Dr. Biczak opened the floor to the board for topics of interest for 2017 RetroDUR initiatives.
    - Opioids
        - MSE equivalence
        - New users versus chronic users
        - Volume of scripts
    - Trending in short term scripts (have the quantities and/or days' supply decreased?).
    - Antipsychotic drugs with coordinating diagnosis
    - Long term use of skeletal muscle relaxants
    - Fluoroquinolone use

Recommendation: These ideas as well as additional ones from Change Healthcare will be presented next meeting. Once initiatives have been chosen, a schedule will be made.

Board Decision: None needed at this time.

7. Clinical Update: Drug Reviews: Laureen Biczak, DO Change Healthcare and Laurie Brady, RPh Change Healthcare

Abbreviated New Drug Reviews:

- None at this time.

Full New Drug Reviews:

a) Adzenys XR® ODT (Amphetamine Extended-release ODT)

- Is included in the Therapeutic Class Review.

Recommendation: PDL placement and criteria will be recommended when TCR is reviewed.

Public Comment: No public comment

Board Decision: Defer decision- to occur with the class review.

b) Spritam® tablets (levetiracetam)

Levetiracetam, the active ingredient of Spritam®, is an antiepileptic drug. Indications and usage is for adjunctive therapy in the treatment of partial onset seizures in patients with epilepsy ≥4 years of age weighing >20kg AND as adjunctive therapy in the treatment of myoclonic seizures in patients ≥12 years of age with juvenile myoclonic epilepsy AND as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients ≥6 years of age with idiopathic generalized epilepsy. The dosage forms are tablets for oral suspension, spearmint-flavored: 250mg, 500mg, 750mg, and 1000mg in blisters; Patients should be educated not to push the tablet through the foil, but rather the foil should be peeled from the blister by bending up and lifting the peel tab around the blister seal. Antiepileptic drugs, including Spritam®, should be withdrawn gradually to minimize the potential of increased seizure frequency. There is no evidence at this time to support that Spritam® is safer or more effective than the currently available, more cost effective medications.

Recommendation: The recommendation is for Spritam® to be non-preferred.

Clinical Criteria:

- Specify dosage forms of Carbamazepine and Dilantin.
- Carbatrol cap, chlorazepate tabs, Dilantin suspension, and lamotrigine ODT moved to non-preferred.
- Spritam® tabs for oral suspension add to non-preferred.

- Remove Valium since it is no longer rebateable.
- Under clinical criteria:
    - Carbatrol and Dilantin suspension will be listed with the other brand name drugs.
    - Lamotrigine ODT- For approval of brand Lamictal ODT, the patient must have a documented intolerance to the generic equivalent.
    - Spritam: medical necessity for a specialty dosage form has been provided AND patient must have a documented intolerance to levetiracetam oral solution.
    - Chlorazepate with be add to the criteria for Fycompa and Potiga. Chlorazepate is also in the Anti-Anxiety Anxiolytics category and will be changed to non-preferred there as well.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Zepatier® tablets (elbasvir and grazoprevir)

Zepatier® is a fixed-dose combination product that contains two direct-acting antiviral agents that work against the hepatitis C virus (HCV) but with distinct mechanisms of action to target HCV at multiple steps in the viral lifecycle. Elbasvir is an inhibitor of HCV NS5A, which is needed for viral RNA replication and virion assembly. Grazoprevir is an inhibitor of the HCV NS3/4A protease, which is needed for the proteolytic cleavage of the HCV encoded polyprotein and for viral replication. Zepatier® is to be used with or without ribavirin for the treatment of chronic hepatitis C virus (HCV) genotypes 1 or 4 infections in adults. It is recommended to obtain hepatic lab testing prior to and during treatment with Zepatier®. In addition, it is recommended to test patients with HCV genotype 1a for the presence of virus with NS5A resistance-associated polymorphisms prior to starting treatment to determine dosage regimen and duration. The most frequently reported adverse events included fatigue (1%) and headache (1%).

Recommendation: The recommendation is the Zepatier® be non-preferred, and require prior authorization to confirm it is being used only in clinical scenarios where more cost effective agents cannot be used.

Clinical criteria:

- Clinical criteria will be deferred until the Epclusa® tablets (sofosbuvir/velpatasvir) review.

Public Comment: No public comment.

Board Decision: Defer decision- to occur with the Epclusa® tablets (sofosbuvir/velpatasvir) review.

d) Epclusa® tablets (sofosbuvir/velpatasvir)

- Epclusa® is a fixed-dose combination tablet containing velpatasvir (an NS5A inhibitor) and sofosbuvir (a nucleotide analog hepatitis C virus (HCV) NS5B polymerase inhibitor). These are both direct-acting antiviral agents against the hepatitis C virus. Sofosbuvir is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is required for viral replication. Velpatasvir is an inhibitor of the HCV NS5A protein, which is also required for viral replication. It is indicated for the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infections: without cirrhosis or with compensated cirrhosis AND with decompensated cirrhosis for use in combination with ribavirin. Epclusa®, like other direct acting antiviral agents, has many drug-drug interactions that need to be considered when initiating or discontinuing therapy.

Recommendation: The recommendation is that Epclusa® tablets be preferred and require prior authorization to confirm appropriate use.

Clinical Criteria:

- Move Olysio® and Sovaldi® to the non-preferred.
- Add Epclusa® to preferred after clinical criteria is met.
- Add Zepatier® to non-preferred.
- Remove Infergen, Rebetp® and the 200mg/400mg of Moderiba® dose pak.
- Under clinical criteria:
  - Add Epclusa and Zepatier to the direct acting agents.
  - Remove- All requests will be reviewed on a case by case basis by the DVHA Medical Director.
  - Add- For approval of a non-preferred agent, the provider must submit clinical documentation detailing why the patient is not a candidate for a preferred direct acting agent regimen.
  - Remove- Quantity limits for peg intron Redipen 4 pens per 28 days. This information is duplicated.

Public Comment: Jeffery Olsen, Highlighted the attributes of Epclusa®.

Board Decision: The Board unanimously approved the above recommendation.

e) Dyanavel XR® suspension (amphetamine)

- Is included in the Therapeutic Class Review.

Recommendation: PDL placement and criteria will be recommended when TCR is reviewed.

Public Comment: No public comment.

Board Decision: Defer decision- to occur with the class review.

f) Quillichew ER® chewable tablets (methylphenidate hydrochloride)

- Is included in the Therapeutic Class Review.

Recommendation: PDL placement and criteria will be recommended when TCR is reviewed.
Public Comment: No public comment.

Board Decision: Defer decision- to occur with the class review.

g) Vraylar® capsules (cariprazine)

- Is included in the Therapeutic Class Review.

Recommendation: PDL placement and criteria will be recommended when TCR is reviewed.

Public Comment: No public comment.

Board Decision: Defer decision- to occur with the class review.

h) Kovaltry® antihemophilic factor (recombinant)

- Kovaltry®, Antihemophilic Factor (Recombinant), is a recombinant human DNA sequence derived, unmodified full length Factor VIII concentrate. Kovaltry® is produced by a genetically engineered Baby Hamster Kidney cell line into which the human Factor VIII gene was introduced together with the human heat shock protein 70 (HSP 70) gene. HSP 70 is an intracellular protein that improves proper folding of the Factor VIII protein. The final product does not contain any preservative. Kovaltry® temporarily replaces the missing clotting Factor VIII needed for effective hemostasis. It is indicated for use in adults and children with hemophilia A (congenital Factor VIII deficiency) for: On demand treatment and control of bleeding episodes; Perioperative management of bleeding; Routine prophylaxis to reduce the frequency of bleeding episodes. Kovaltry® is not indicated for the treatment of von Willebrand disease.

Recommendation: The recommendation is for Kovaltry® to be non-preferred.

Clinical criteria:

- Add Kovaltry to non-preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

i) Idelvion® coagulation Factor IX (recombinant)

- Coagulation Factor IX (recombinant), Albumin Fusion Protein (rIX-FP), the active ingredient of Idelvion®, is a purified protein produced by recombinant DNA technology. It is manufactured without the use of proteins derived from human or animal source materials and is a glycoprotein consisting of 1018 amino acids secreted by a genetically engineered Chinese hamster ovary (CHO) cell line. Idelvion® temporarily replaces the missing coagulation Factor IX needed for effective hemostasis. Fusion with recombinant albumin extends the half-life of Factor IX. It is recommended in children and adults with hemophilia B (congenital Factor IX deficiency) for: on-demand control and prevention of bleeding episodes; perioperative management of bleeding; and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Idelvion® is not indicated for immune tolerance induction in patients with hemophilia B. Dose and duration of treatment depends on the severity of Factor IX deficiency, the location and extent of bleeding, and the patients clinical condition, age, and recovery of Factor IX. The required dose of Idelvion® for treatment of bleeding episodes is determined using a formula.

Recommendation: The recommendation is for Idelvion® to be non-preferred.

Clinical criteria:

- Add Idelvion® to non-preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

j) Xeljanz XR® tablets (tofacitinib)

- Tofacitinib, the active ingredient of Xeljanz® XR, is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes that transmit signals from cytokines or growth factor-receptor interactions to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs), which modulate intracellular activity including gene expression. Tofacitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs. It is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying

antirheumatic drugs (DMARDs). Xeljanz® XR has a box warning regarding the increased risk of serious infections that may lead to hospitalization or death and the increased risk of malignancy.

Recommendation: The recommendation is for Xeljanz XR® to be non-preferred.

Clinical criteria:

- Add Xeljanz® XR to non-preferred with quantity limit of 1 tablet/day.
- Add Xeljanz® XR to the Xeljanz additional criteria.
- Add- For approval of Xeljanz XR, patient has not been able to tolerate or adhere to twice daily dosing of immediate release Xeljanz, resulting in significant clinical impact.
- Add on the preferred side under Oral- All products require PA.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

8. Therapeutic Drug Classes – Periodic Review Laurie Brady, RPH Change Healthcare

a) Antidepressants, SSRIs

- New drug **Brisdelle® capsules (paroxetine)**
  - Paroxetine (Brisdelle®) is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause. The mechanism of action of paroxetine (Brisdelle®) for the treatment of VMS is not known.
- A 2015 systematic review and meta-analysis by Sharma et al included double-blind, placebo controlled trials to assess for the serious harms of SSRIs and SNRIs. Outcomes assessed included mortality and suicidality, while secondary outcomes were aggressive behavior and akathisia. Drugs assessed included duloxetine, fluoxetine, paroxetine, sertraline, and venlafaxine. Altogether, 10258 patients received an active drug and 6832 received placebo. Eleven of the studies included children and adolescents (12% of the patients). Overall, differences in mortality, suicidality, and akathisia were not significant, but patients taking antidepressants had more aggressive behavior as compared to those taking placebo**.**

Recommendation:

- No changes at this time.

Clinical Criteria:

- Under clinical criteria:

- Combine Celexa, fluvoxamine CR, Lexapro, Paxil tablet, Pexva, Paroxetine CR, Paxil CR, Prozac, Sarafem, and Zoloft. Clarify that One trial must be the generic formulation or IR formulation if CR formulation requested
- Remove individual criteria for fluvoxamine CR, Pexva, ParoxetineCR, Paxil CR and Sarafem.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

b) Antidepressants, Other

- In 2016, an FDA Drug Safety Communication bulletin was disseminated regarding the brand name change of Brintellix® (vortioxetine). Due to the risk of prescribing and dispensing errors from name confusion with the brand name medication Brilinta® (ticagrelor), the US FDA has approved a brand name change for Brintellix®. The new brand name of the drug is Trintellix®. Therefore, brand name Brintellix® has been changed within this class review to Trintellix®, to reflect this new change.
- A 2015 network meta-analysis by Khoo et al included 76 randomized controlled trials to assess for the efficacy and tolerability of new generation antidepressants for treatment of MDD in Singapore.
- No significant changes.

Recommendation:

Clinical criteria for MAO Inhibitors:

- Remove- Limitations: Chlordiazepoxide/amitriptyline and amitriptyline/perphenazine combinations are not covered. Generic agents may be prescribed separately.

Clinical criteria for TCA:

- Move Imipramine Pamoate capsule to non-preferred.
- Remove Tofranil PM®* and Vivactil®*.
- On preferred side remove- compare to Vivactil®.
- Under clinical criteria:
  - Add- Criteria for approval of ALL non-preferred drugs: The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR The patient meets additional criteria as outlined below.
  - Remove duplication of above statement under individual drugs.

- Add- Imipramine Pamoate: The patient has had a documented side effect, allergy, or treatment failure to 3 preferred TCAs, one of which must be imipramine tablets.

Clinical criteria for Miscellaneous:

- Remove Budeprion® SR, Budeprion XL, formerly Ludiomil® from preferred.
- Remove Oleptro® ER tablets and Wellbutrin®* from non-preferred.
- Move Nefazodone to non-preferred.
- Under clinical criteria
  - Add- Criteria for approval of ALL non-preferred drugs: The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR The patient meets additional criteria as outlined below.
  - Remove duplication of above statement under individual drugs.
  - Add- Nefazodone: The patient has had a documented side effect, allergy, or inadequate response to at least 3 different antidepressants from the SSRI, SNRI and/or Miscellaneous Antidepressant categories (may be preferred or non-preferred)
  - Clarify Aplenzin - The patient has had a documented side effect, allergy, or inadequate response to at least 3 different antidepressants from the SSRI, SNRI and/or Miscellaneous Antidepressant categories (may be preferred or non-preferred), one of which must be bupropion XL.

Clinical Criteria for SNRI:

- Remove duplicate Venlafaxine ER tablet under non-preferred.
- Under clinical criteria:
  - Add- Criteria for approval of ALL non-preferred drugs: The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR The patient meets additional criteria as outlined below.
- Remove duplication of stabilization statement under individual drugs.
- Remove therapeutic categories and “may be preferred or non-preferred” statement under non-preferred criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Antipsychotics

- New drug **Vraylar® capsules (cariprazine)**

- No significant changes.

Recommendation: The recommendation is for Vraylar® capsules to be non-preferred.

Clinical Criteria for Typicals:

- Remove- formerly Thorazine®, formerly Prolixin®, formerly Stelazine® and formerly Prolixin® decanoate from product descriptions.

Clinical Criteria for Atypical &Combinations (Adults ≥ 18 years old)

- Add Vraylar® FDA maximum recommended dose =6mg/day, Quantity limit=1 capsule/day to non-preferred.
- Removed Quetiapine.
- Under clinical criteria:
    - Criteria for approval of ALL non-preferred drugs: patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization.) OR patient meets additional criteria outlined below. Note: Trazodone dosed at < 150 mg/day will not be considered as a trial for adjunct treatment of MDD or any anxiety disorder. Bupropion will not be considered as a trial for adjunct treatment of any anxiety disorder.
    - Remove duplication of stabilization statement under individual drugs.
    - Remove Saphris criteria and group with Invega criteria.
    - Add to the Latuda criteria- The patient is pregnant and the diagnosis is schizophrenia/schizoaffective disorder or Bipolar I depression. OR The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR The indication for use is schizophrenia/schizoaffective disorder. AND The patient has had a documented side effect, allergy or treatment failure with two preferred products.
    - Remove under Quetiapine/Seroquel the therapeutic classes required for therapeutic failure (SSRI, SNRI, tricyclic and/or Miscellaneous antidepressant categories).

Clinical Criteria for Atypical &Combinations (Children < 18 years old)

- Under clinical criteria

- Add - Criteria for approval of all drugs: Medication is being requested for one of the target symptoms or diagnoses listed above AND the patient is started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) OR patient meets additional criteria outlined below. Note: all requests for patients <5 years will be reviewed by the DVHA medical director.
- Remove duplication of clinical criteria listed under each drug.
- Add aripiprazole to the Abilify criteria and add- For approval of brand Abilify, the patient must have a documented intolerance to the generic equivalent.
- Add accepted diagnosis for approval- Disruptive Mood Dysregulation Disorder and Major Depressive Disorder with psychotic features.

Public Comment: Kelly Brodrick from Suniovon Highlight the attributes of Latuda
Kelly Broderick from Sunovion: Highlight the attributes of Lurasidone
Irma Saliu from Allergan: Highlighted the attributes of Vraylar
Shaffee Bacchus from Janssen: Highlighted the attributes of Invega Sustenna/Trinza

Board Decision: The Board unanimously approved the above recommendations with the following amendments:

- Vraylar® will be added to the list of medications that will not be approved in children <18 years of age.
- Quetiapine at doses of 50mg or less will remain non-preferred and require PA.
- Under Latuda clinical criteria for a diagnosis of Bipolar 1 Depression, the statement will be added "OR the prescriber feels that none of the preferred products would be an appropriate alternative because of a pre-existing medical condition such as obesity or diabetes."

d) Stimulants

- New drug **Adzenys XR® ODT (amphetamine extended-release ODT)**
- New drug **Dyanavel XR® suspension (amphetamine)**
- New drug **Quillichew XR® chewable tablets (methylphenidate hydrochloride)**
- No significant changes.

Recommendation: The recommendation is for Adzenys XR® ODT and Quillichew XR® to be preferred and Dyanavel XR® suspension to be non-preferred.

Clinical Criteria for ADHD and Narcolepsy Cataplexy Medications Short/Intermediate Acting Stimulants:

- Add Methylin chewable tablets and solution to preferred.
- Add Methylphenidate tablets to preferred.
- Remove Methylin ER.
- Move Dextroamphetamine IR to non-preferred.
- Add methylphenidate chewable tablets and solution to non-preferred.
    - Under clinical criteria:
        - Add Clinical Criteria for all non-preferred drugs: patient has a diagnosis of ADD, ADHD or narcolepsy AND patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR patient meets additional clinical criteria outlined below.
        - Remove duplication of clinical criteria listed under each drug.
        - Add- Methylphenidate chewable: patient is not a candidate for a long acting methylphenidate chewable tablet (Quillichew®) or oral suspension (Quillivant XR®).
        - Add- Methylphenidate solution: patient has a documented intolerance to Methylin solution.
        - Add- Dextroamphetamine IR, Zenzedi, Evekeo: the patient has had a documented side-effect, allergy, or treatment failure of at least 2 preferred agents.
        - Clarify- Ritalin and Ritalin SR: patient has had a documented intolerance to the preferred equivalent. For Ritalin SR, this is Metadate ER, For Ritalin this is methylphenidate tablets.

Clinical Criteria for ADHD and Narcolepsy Cataplexy Medications Long Acting Stimulants:

- Add Quillichew ER™ (methylphenidate IR/ER, 30:70%) chewable tablets to preferred.
- Add Adzenys XR® ODT (amphetamine/dextroamphetamine SR 24 HR, IR/ER, 50:50%) (QL=1 cap/day) to preferred.
- Add Dyanavel™ XR suspension (amphetamine/dextroamphetamine SR) (QL=240ml/30days) to non-preferred.
- Move Dextroamphetamine 24 hr SR to non-preferred.
    - Under clinical criteria:
        - Add- Clinical criteria for all non-preferred drugs: the patient has a diagnosis of ADD, ADHD or narcolepsy AND has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) OR meets the additional clinical criteria outlined below.
        - Remove duplication of clinical criteria listed under each drug.

- Add - Dexedrine CR, dextroamphetamine SR, Dyanavel: patient must have a documented intolerance to one preferred amphetamine product. For approval of brand Dexedrine CR, the patient must also have a documented intolerance to the generic equivalent.

Clinical Criteria for ADHD and Narcolepsy Cataplexy Medications Miscellaneous:

- Move Clonidine ER (compare to Kapvay®) (authorized generic, labeler code 59212, is the only preferred form) to preferred with a Qty limit = 4 tabs/day.
- Add Armodafinil (compare to Nuvigil®) Qty limit: 50 mg = 2 tablets/day; 150 mg/200 mg/250 mg = 1 tablet/day to non-preferred.
- Add Kapvay® (clonidine extended release) Tablet to non-preferred with Qty limit = 4 tablets/day.
    - Under clinical criteria:
        - Under Nuvigil, Armodafinal add- AND if the request is for armodafinil, the patient has a documented intolerance to brand Nuvigil.
        - Update under Kapvay and non-authorized generic clonidine ER: patient must have had a documented intolerance to the authorized generic.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

e) Analgesics, SA Narcotics

- No new drugs.
- No significant changes.
- In March, 2016, the FDA announced enhanced class-wide warnings for immediate-release opioid pain medications about the serious risks of misuse, abuse, addiction, overdose and death. The updated indication clarifies that because of these risks, immediate-release (IR) opioids should be reserved for pain severe enough to require opioid treatment and for which alternative treatment options (e.g., non-opioid analgesics or opioid combination products, as appropriate) are inadequate or not tolerated. The recent CDC guidelines echo this statement.

Recommendation: No recommendation.

Clinical Criteria:

- Removal of all drugs that are no longer covered or rebateable.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

f) Analgesics, LA Narcotics

- Belbuca® and Xtampza® ER are now included in the class review.
- Xtampza® ER has yet to come up for new drug review in Vermont yet.
- Avinza®, a brand name of morphine, has been discontinued by the manufacturer and has been removed from this class review.

Recommendation: Add Fentanyl patch in strengths 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr to non-preferred.

Clinical Criteria:

- Add 75 mcg/hr, 100 mcg/hr (QL=30 patches/30 days) to preferred under Fentanyl patch.
- Add 75 mcg/hr, 100 mcg/hr (QL= 30 patches/30 days) to non-preferred under Duragesic.
    - Under clinical criteria:
        - Remove duplications of the statement "patient has a diagnosis of pain that requires daily, around-the-clock, long-term treatment and for which alternative treatment options are inadequate."
        - Fentanyl patches 37.5mcg/hr, 62.5mcg/hr, 87.5mcg/hr: provider must submit clinical rationale detailing why the patient is unable to use a combination of the preferred strengths.
        - Methadone liquid: Patient must have a medical necessity for an oral liquid (i.e. swallowing disorder, inability to take oral medications) AND the initial daily dose does not exceed 30mg OR patient has been started and stabilized on the requested oral liquid medication.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

9. New Managed Therapeutic Drug Classes

- None at this time.

10. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products

- **Nucala® injection (mepolizumb)**
    - Remove- The patient has a documented side effect, allergy, or treatment failure to Xolair from the clinical criteria of Nucala

- **2016/17 Seasonal Influenza Vaccine: Joseph Olinzock, DVHA Pharmacy Intern**

- For SEASONAL Influenza Vaccine INJECTION Inactivated Influenza Vaccine, Trivalent (IIV3), Standard Dose (egg based) Afluria injection and Fluvirin injection are preferred.
- For Inactivated Influenza Vaccine, Quadrivalent (IIV4), Standard Dose (egg based) Fluarix Quadrivalent injection, Flulaval Quadrivalent injection, Fluzone Quadrivalent injection and Fluzone Intradermal injection are preferred.
- For Inactivated Influenza Vaccine, Trivalent (IIV3), Standard Dose (egg based) Fluad Injection is non-preferred
- For Inactivated Influenza Vaccine, Trivalent (IIV3), High Dose (egg based) Fluzone High-Dose® Injection is non-preferred.
- For Recombinant Influenza Vaccine, Trivalent (RIV3) (egg FREE) Flublok® Injection is non-preferred.
- Inactivated Influenza Vaccine, Quadrivalent (ccIIV4), Standard Dose (cell culture based) (NOT egg free) Flucelvax® Quadrivalent injection is non-preferred.
    - Under clinical criteria
        - Remove Flumist criteria.
        - Update Flucelvax Quadrivalent: Prescriber provides clinical rationale why one of the preferred influenza vaccines cannot be used.
        - Update Flublok: Patient must have a documented severe reaction to egg based influenza vaccine.
- Add Fluzone High Dose, Fluad: Vaccine is being requested for influenza prophylaxis during flu season AND patient is ≥ 65 years old AND Prescriber provides clinical rationale why one of the preferred influenza vaccines cannot be used. Note: The CDC and its Advisory Committee on Immunization Practices (ACIP) have not expressed a preference for any flu vaccine formulation for this age group.

11. General Announcements: Laurie Brady, RPH GHS/Change Healthcare

- Selected FDA Safety Alerts

    - Defer until next meeting.

12. Adjourn: Meeting adjourned at 8:40p.m.